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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/446,298	06/12/00	LUBDA	D MERCK2047

IM22/0815
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EXAMINER	
ROCHE, L	

ART UNIT	PAPER NUMBER
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1771
DATE MAILED:
08/15/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/446,298	LUBDA ET AL.
	Examiner Leanna Roche	Art Unit 1771

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-3 is/are rejected.

7) Claim(s) 2 and 3 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed July 18, 2000 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of the document CH 507724 which is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

2. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

3. The disclosure is objected to because of the following informalities: the disclosure makes reference to Figures 1, 2 and 3, but no drawings were filed with the present application. Appropriate correction is required.

Drawings

4. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 2 and 3 provide for the use of a monolithic sorbent, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 2 and 3 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Frechet et al. (USPN 5334310).

Frechet is directed to a continuous liquid chromatography column containing a separation medium comprised of a plug containing small pores less than 200nm in diameter and large pores greater than 600nm in diameter. The tube containing the separation medium may be comprised of rigid polymers that are substantially rigid so that there is no change in the volume of the column during the polymerization reaction.

Frechet also discloses that the use of polytetrafluoroethylene as a casing material for liquid chromatography columns is known. It is known in the art that polytetrafluoroethylene is resistant to both pressure and liquid permeation.

Frechet, however, does not specifically state that their rigid polymer casing material is liquid-impermeable. It appears that continuous liquid chromatography column of Frechet is substantially identical to the presently claimed liquid chromatography column. Thus, it is believed by the examiner that the liquid chromatography column of Frechet would inherently possess a liquid-impermeable casing as claimed by Applicant. See *In re Best*, 195 USPQ 433 footnote 4 (CCPA 1977) as to the providing of this rejection under 35 USC 103 in addition to the rejection made under 35 USC 102. It is well known in the art that in order to efficiently separate a sample by liquid chromatography, the solvent and sample must be capable of flowing freely through the liquid chromatography column and interference between the packing material and casing of the column with the sample must be minimized. Therefore, it would have been obvious to a person having ordinary skill in the art at the time this invention was made to have used a rigid polymer casing material that is liquid

impermeable, motivated by the desire to produce a chromatography column with minimal sample interference.

13. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al. (USPN 5624875) in view of Schick (USPN 5482628).

Nakanishi is directed to an inorganic porous material having interconnected macropores with a median diameter larger than 0.1 µm and having mesopores with a median diameter between 2 and 100 nm in the walls of the macropores. The inorganic porous material of Nakanishi may be used to form liquid- and gas-chromatographic columns.

Nakanishi explains that their claimed inorganic porous material may be combined with appropriate column design to provide mechanical support to the brittle inorganic porous column, but does not specifically disclose a liquid-impermeable, pressure resistant plastic casing surrounding the inorganic porous material (Column 7 lines 23-29). Schick is directed to a column for liquid chromatography comprised of a tube of polyetheretherketone (PEEK) or polytetrafluoroethylene (TEFLON) filled with any one of a number of packing materials. The PEEK tube provides a high degree of chemical inertness and is chemically inert to most common solvents (Schick Column 6 lines 42-49). Additionally, PEEK columns have been known to resist pressures of up to 2000 psi (Schick Column 3 lines 41-50). It is known in the art that TEFLON is resistant to both liquid permeation and pressure. Liquid impermeability prevents the solvent from interfering with sample separation. Pressure resistance prevents the column from collapsing and increases the durability of the column. Therefore, it would have been

obvious to the skilled artisan at the time this invention was made to combine the teachings of Nakanishi and Schick, motivated by the desire to produce a chromatography column with low flow resistance and high reproducibility which is also durable and resistant to sample separation interference.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 95/03256 discloses the claimed monolithic sorbent material. DE 1955276 discloses a separation column for liquid-liquid chromatography comprised of a corrosion-resistant plastic, such as TEFLON, column.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leanna Roche whose telephone number is 703-308-6549. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Blaine Copenheaver can be reached on 703-308-1261. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



lmr

August 10, 2001



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